JUL 2 4 2001

K011999

CONFIDENTIAL
Data Critical Corporation
FlexView™ Clinical Monitoring System
Special 510(k): Device Modification

510(k) SUMMARY

This 510(k) summary is submitted in accordance with 21 CFR 807.92.

Submitter's Name:	Data Critical Corporation
Submitter's Address:	19820 North Creek Parkway Bothell, WA 98011
Telephone:	425-482-7000
Fax:	425-482-7010
Contact Person:	Teresa M. Davidson
Date Prepared:	June 26, 2001
Device Trade Name:	FlexView™ Clinical Monitoring System
Device Classification Name:	System, Network and Communication, Physiological Monitors
Device Classification:	Class II
Predicate Device(s):	FlexView™ Clinical Monitoring System (K003998)

Device Description
The FlexView™ Clinical Monitoring System is a PC based central monitoring station used to acquire information from primary medical devices (pulse oximeters, infusion pumps and ventilators) and redisplay it on a single monitor in a central location. It allows the remote monitoring of multiple medical devices simultaneously and provides secondary annunciation of the alarms from the primary medical devices.

Intended Use
The FlexView™ Clinical Monitoring System is intended for use as a secondary annunciation of compatible primary medical device alarms.

Indications For Use
The FlexView™ Clinical Monitoring System is intended for use as a secondary annunciation of compatible primary medical device alarms.

The FlexView™ Clinical Monitoring System is for use as an accessory to primary medical devices and is currently compatible with pulse oximeters, infusion pumps and ventilators. The FlexView™ Clinical Monitoring System is to supplement and not replace any part of the current primary medical device monitoring procedure.

The FlexView™ Clinical Monitoring System is for use by healthcare professionals trained in the use of the primary medical devices that are being monitored. The FlexView™ Clinical Monitoring System is not considered to be diagnostic without skilled interpretation and does not replace physician's care.

The FlexView™ Clinical Monitoring System is for use with patient populations being monitored by healthcare professionals utilizing compatible pulse oximeters, infusion pumps and ventilators.

The FlexView™ Clinical Monitoring System is for use in healthcare facilities such as hospitals, outpatient clinics or free standing surgical centers.

Performance Data
The safety and effectiveness of the modified FlexView™ Clinical Monitoring System described in this submission has been demonstrated through risk analysis and verification and validation testing. Test results demonstrated that the modified FlexView™ Clinical Monitoring System performance, functionality and safety characteristics are substantially equivalent to the predicate device.

Conclusions
Based on the information provided in this submission, the modified FlexView™ Clinical Monitoring System is substantially equivalent to the predicate device and does not raise new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 24 2001

Ms. Teresa M. Davidson
Director of Regulatory Affairs and Quality Assurance
Data Critical Corporation
19820 North Creek Parkway
Bothell, WA 98011

Re: K011999
Trade Name: FlexView™ Clinical Monitoring System
Regulation Number: 21 CFR 870.2300
Regulatory Class: II (two)
Product Code: 74 MSX
Dated: June 26, 2001
Received: June 27, 2001

Dear Ms. Davidson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the

Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4645. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K011999

Device Name: FlexView™ Clinical Monitoring System

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011999

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)